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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,054	11/01/2000	Robert D'Amato	43170-249244	3798
20583	7590	04/05/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			LEWIS, AMY A	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/704,054	Applicant(s) D'AMATO, ROBERT	
	Examiner Amy A. Lewis	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23,25-31 and 33-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23,25-31 and 33-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/31/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Case***

The Remarks, filed 31 October 2005, have been entered into the application.

Claims 23, 25-31 and 33-70, as filed 27 January 2005 are pending.

### ***Objection to the Drawings***

The drawings are objected to because Figures 1-5, filed on 1 November 2000, are do not have designations for each individual structure depicted within a Figure; a suggested correction would be, in Figure 1 for example, a designation of structures a) through o). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

*Response to Applicant's arguments, filed 31 October 2005:*

1) Rejection of claims 23, 25-31 and 33-58 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,629,327 has been withdrawn in view of the approved terminal disclaimer, filed on 31 October 2005.

2) Claims 23, 25-31 and 33-58 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sugiura et al. Applicant's arguments have been fully considered, but are not persuasive. Therefore the rejection is *maintained* for the reasons of record and further below.

Applicant argues that Sugiura fails to render the claims obvious. Applicant argues that the "moderate inhibitory effect [of thalidomide] on Lewis bladder carcinoma (page 59) and slight inhibitory effect on 6 other tumors," taught by Sugiura and cited by the Examiner, lacks the "legally required suggestion and expectation of success" (see: Remarks p. 3). In addition, Applicant argues that "because the results of Sugiura are so poor and no significant degree of antineoplastic activity was demonstrated in animal, much less humans," (see: Remarks p. 3-4) Sugiura fails to suggest the claimed invention to those of ordinary skill in the art. This is not persuasive. Sugiura nonetheless teaches the inhibition of growth of tumors sensitive to thalidomide, i.e. inhibition of Lewis bladder carcinoma; the effectiveness of thalidomide against other tumor types is not at issue in the instant claims. Therefore the rejection is maintained.

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3) Claims 23, 25-31 and 33-58 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mückter. Applicant's arguments have been fully considered, but are not persuasive.

Therefore the rejection is *maintained* for the reasons of record and further below.

Applicant argues that Mückter does not suggest the claimed invention and would not have provided a person of ordinary skill in the art with the suggestion or reasonable expectation of success that thalidomide is effective against tumors in animals, much less humans" (see Remarks p. 5, paragraph 3). Applicant supports this argument by pointing out that in the experiments on rats, thalidomide showed some response in delaying the appearance and growth of tumors over a period of four or five weeks, but abated after about six months of treatment. Applicant additionally argues that in the Mückter reference, "thalidomide did not influence either the number or the growth of tumors in mice" (see Remarks p. 5, last paragraph).

The argument is not persuasive. As stated in the previous Office Actions (see the action dated 27 July 2004), Mückter discloses (page 533, both columns) that the latent period of manifestation of tumors increased with thalidomide and that thalidomide retarded in a most impressive fashion the manifestation and growth of tumors induced in rats by the carcinogen DMBA. Even though the effect of thalidomide was "limited by the size of the tumors at the time of first application, and by the duration of treatment (see Mückter abstract), the reference nonetheless teaches treatment of the DMBA induced tumors; effectiveness of the treatment is not at issue in the claims.

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In response to the argument that thalidomide was not effective in the mouse model of tumor growth in the Mückter reference, as previously stated, the Sprague Dawley rat is a general model for the study of health and disease and Sprague Dawley rats are considered relevant animal models for the study of breast cancer (see: Office Action dated 4 May 2005, p. 2 last paragraph). Thus, one of ordinary skill in the art would have given more weight to the guidance in the Mückter reference regarding the rat models, which indicated effectiveness, as opposed to the mouse models.

Therefore, the rejection is maintained.

4) Claims 23, 25-31 and 33-58 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mau'ad. Applicant's arguments have been fully considered, but are not persuasive. Therefore the rejection is *maintained* for the reasons of record and further below.

Applicant argues that Mau'ad does not teach or suggest that the single use of thalidomide is effective against any kinds of cancer, and that the reference tested the effects of combinations of thalidomide and various other agents (see Remarks p. 6).

Applicant's argument is not persuasive. In claim 23, the phrase "comprising," is open-claim language. "The transitional phrases 'comprising', 'consisting essentially of' and 'consisting of' define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. The transitional term 'comprising', is synonymous with 'including,' 'containing,' or 'characterized by,' is inclusive or open-ended and *does not exclude additional, unrecited elements* or method steps. See, e.g., *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66

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USPQ2d 1631, 1634 (Fed. Cir. 2003). The transition phrase ‘comprising’ in a method claim indicates that the claim is open-ended and allows for additional step” (MPEP § 2111.03 [R-2] Transitional Phrases). This the claim allows for additional elements/agents, and therefore Mau’ad teaches treatment of various types of cancer with thalidomide. Thus the rejection is maintained.

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*Conclusion*

Claims 23, 25-31 and 33-58 are rejected. No claims are allowed.

Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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